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Attorney's Docket No.: 11984-005001

REMARKS

Applicants respectfully request entry of the remarks submitted herein. Claims 1-51 are currently pending. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §103 Rejections

Claims 1-3, 6-10, 13-21, 22-25, 28-33, 36-39 and 43-51 stand rejected under 35 U.S.C. §103 as being unpatentable over the Poehlman reference (document AEE from Applicant's 1449) in view of the Reuters reference (Chicago Sports Final Ed., pg. 4, September 3, 1998). This rejection is respectfully traversed.

Proper analysis under 35 U.S.C. §103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should carry out the claimed process, *and* (2) whether the prior art also would provide that in so carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 288, 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, there must be some teaching, suggestion, or incentive to make the claimed invention beyond the mere disclosure of individual components of the claimed invention either separately or in other combinations. *Northern Telecom, Inc. v Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990). A teaching, suggestion, or incentive to make the claimed combination must come from the prior art, and not the Applicant's invention itself. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). That is, the invention must be viewed not with the blueprint drawn by the inventor, but in view of the prior art. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985). The courts have emphasized that combining prior art references without evidence of a suggestion or motivation to do so "simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight . . ." *In re Dembiczak*, 175 F.3d. 994, 999 (Fed. Cir. 1999) (citations omitted).

With respect to claim 1, the Examiner asserted that the Poehlman reference discloses the method steps of preparing a non-genetically modified processed food product comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less genetically modified seed (page 451, col. 2, sections b and d), and

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harvesting, processing and certifying the crop. The Examiner indicated that the Poehlman reference does not disclose certifying that the seed contains 5% or less of genetically modified crop material, and asserts that the Reuters reference discloses the motivation to certify for contamination by genetically modified crop material. As to the dependent claims, the Examiner alleged that it would be obvious to one of ordinary skill in the art to modify the method described in the Poehlman reference using the Reuters reference to arrive at each claimed limitation.

Applicants strongly disagree with the Examiner's statements. The Poehlman reference is a textbook about plant breeding. The Poehlman reference discusses, *inter alia*, production of certified seed, which results from plant breeding. Applicants submit that the Poehlman reference discloses the general process of breeding field crops and describes the process of generating breeder seed, foundation seed, and registered seed. Such classes of seed typically are for use by other breeders, for further reproduction by foundation seed growers, or for sale to farmers, respectively. The Poehlman reference describes methods for breeding and certifying new seed varieties. The seed stocks resulting from the new varieties produced by the methods disclosed in the Poehlman reference can then be provided to growers (see page 449, column 2 and page 450, column 2). However, the seed stocks described in the Poehlman reference are merely the starting point for the methods of the claimed invention.

The Poehlman reference does not discuss problems encountered in producing a non-genetically modified crop and ensuring that the crop is not contaminated by genetically modified grain. The Poehlman reference also does not discuss problems in processing a non-genetically modified crop to ensure that it does not become contaminated by genetically modified grain. For any given variety of plant, Applicants submit that the visual screening methods described in the Poehlman reference are inadequate to distinguish non-genetically modified crops and processed grain from genetically modified crops and processed grain. See, e.g., StratSoy Soybean Answers, at http://web.aces.uiuc.edu/faq/faq.pdl?project_id=28&faq_id=590. Applicants further submit that the production, processing and marketing of a harvested crop are not the responsibility of a seed breeder or seed certification agencies. Therefore, the Poehlman reference cannot disclose or suggest methods related to production, processing, and marketing of non-genetically modified processed grain such that contamination by genetically modified grain was present at only low levels or was absent.

With respect to the Poehlman reference, the Examiner repeatedly includes the language “**and visually inspecting field for any crop plant growing and eliminating off-types whether they be genetically or nongenetically modified**” (emphasis in original), implying that the Poehlman reference teaches or discloses such a step. Applicants respectfully submit that the Poehlman reference does not, and cannot, teach or disclose such a step.

First, the Poehlman reference cannot suggest a method for preparing non-genetically modified processed grain having a low level of contamination by genetically modified seeds because genetically modified seeds are not “off-types,” “Other Seed,” “Weed Seed” or “Noxious Seed.” See van Duijn et al., 1999, “Detection Methods for Genetically Modified Crops,” *Food Control*, 10:375-378. Thus, the teachings in the Poehlman reference concerning breeding new plant varieties and monitoring the levels of “Other Seed” “Weed Seed” and “Noxious Seed” in the seed stock of such varieties provides no disclosure regarding preparing non-genetically modified processed grain from a harvested crop and certifying such processed grain, nor does the Poehlman reference disclose preventing contamination of non-genetically modified processed grain by genetically modified grain. Thus, it could not be obvious, in view of the Poehlman reference, to extend a determination of the percentage level of “off-types,” “Other Seed,” “Weed Seed” or “Noxious Seed” in a seed stock to the percentage of genetically modified seeds in processed grain. Moreover, it could not be obvious in view of the Poehlman reference to certify that the percentage of genetically modified seeds in processed grain from non-genetically modified seeds is 5%, 1%, 0.1% or 0.01%, or less.

Second, the Poehlman reference cannot suggest a method for preparing non-genetically modified processed grain having a low level of contamination by genetically modified seeds because, as of the date of the Poehlman reference (1979), genetically modified seeds did not exist. As discussed in news articles from the *PR Newswire* (January 18, 1983) and *The Washington Post* (April 30, 1983), the first genetically modified crop plants were produced in 1983. Research by groups including Fraley et al. (*Proc. Natl. Acad. Sci. USA*, 80:4803-4807, 1983) and Herrera-Estrella et al. (*EMBO*, 2:987-995, 1983) produced the first genetically modified plants. See, IDS submitted January 12, 2001. Thus, the discussion in the Poehlman reference of methods of producing certified seed cannot provide any suggestion to practice the claimed methods.

The Reuters reference is a short newspaper article covering an advisory issued by Arthur Daniel Midlands to farmers and grain merchants. This advisory was issued "with harvest only days away," and advised farmers and grain merchants to "segregate non-genetically enhanced crops to preserve their identity" (emphasis added). The Reuters reference briefly mentions physical separation of harvested crops, but does not provide any motivation to combine the desire to "segregate non-genetically enhanced crops" with any particular method of doing so. In addition, the Reuters reference provides no reasonable expectation that one would be successful in segregating genetically modified and non-genetically modified crops.

The differences between seed certification as discussed in the Poehlman reference and conventional farming practices are recognized by Poehlman himself. For example, the Poehlman reference states that small grains, rice, and soybean crops are planted by farmers "on large acreages." See page 456, left-hand column. In contrast, the Poehlman reference teaches that breeder seed involves merely "several hundred" plants or "several hundred" rows. See page 456, right-hand column. That is, the scale of operations involved in producing a crop is vastly larger than the scale of operations involved in producing planting seed as described in the Poehlman reference.

As to claim 22 and 36, the Examiner asserted that the Poehlman reference discloses the method steps of growing and harvesting a pure line of seed for a processed food product comprising certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less off-types modified seed (page 451, col. 2, sections b and d), and harvesting, processing and certifying the crop. The Examiner admitted that the Poehlman reference does not disclose certifying that the seed contains 5% or less of non-genetically modified crop material when the pureline is genetically modified seed, but the Examiner alleged that the Reuters reference discloses the motivation to certify for contamination by genetically modified crop material. The Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed in the Poehlman reference by certifying for contamination by either genetically modified or non-genetically modified crop material so as to be able to sell their harvest.

As to claim 43, the Examiner asserted that the Poehlman reference discloses the method steps of growing and harvesting a pure line of seed used for a processed food product comprising

certifying the seed was planted and grown under conditions effective for harvesting a crop containing 5% or 1% or less off-types modified seed (page 451, col. 2, sections b and d), and harvesting, processing and certifying the crop. The Examiner admitted that inspecting the processing facility before processing the crop to maintain a product to contain 5% or less of genetically modified crop material is not disclosed, but alleged that the Reuters reference discloses the motivation to maintain pure crop material from a farmer's field to a food product. The Examiner concluded, therefore, that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed in the Poehlman reference by inspecting and keeping the processing food plants clean. The Examiner asserted that the Reuters reference provides the motivation to modify the method disclosed in the Poehlman reference so that food producers can sell their product.

Applicants submit that even if the Poehlman reference and the Reuters reference were to be combined, one of ordinary skill in the art would not have had a reasonable expectation of success in achieving the claimed methods. The Poehlman reference contains no teaching or suggestion concerning certifying that a non-genetically modified crop contains 5% or less genetically modified seeds. The Reuters reference merely mentions physical separation of harvested crops, and contains no specific suggestion concerning the methods that can be used to separate genetically modified from non-genetically modified plants. Further, the Reuters reference provides no reasonable expectation that farmers and grain merchants will be successful in segregating genetically modified and non-genetically modified crops. In the absence of a reasonable expectation of success, the claimed methods are patentably non-obvious even if the Poehlman reference and the Reuters reference are combined.

Contrary to the Examiner's assertion, the seed certification process discussed in the Poehlman reference is not applicable to the subject matter of the claimed invention. As indicated in the enclosed Declaration under 37 CFR §1.132 by Robert H. Peterson, the discussion in the Poehlman reference relates to state seed certification laws. Such laws apply to seed intended for sowing (*i.e.*, planting). Such laws do not apply to seeds of a harvested crop, because such seeds are not intended to be sown. Peterson Declaration, #17 and 18.

Although the Poehlman reference discusses seed certification, it does not disclose farming practices. There is no indication whatsoever in the Poehlman reference that seed

certification equates to farming and grain processing practices. Contrary to the Examiner's view, it is the opinion of Mr. Peterson, a person with extensive training and experience in plant breeding, that seed certification as described in the Poehlman reference is not applicable to the methods recited in claims 1-51. Peterson Declaration, #18 and 19. That is, the Poehlman reference would not have applied to the problem of preventing contamination by genetically modified seed when growing, harvesting, and processing a crop.

In view of Mr. Peterson's Declaration and the remarks above, Applicants respectfully submit that the Poehlman reference is nonanalogous art. *In re Deminski* (796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986)) applied a two-step test to determine whether a prior art reference was nonanalogous and thus not relevant in determining obviousness. According to the two-step test, it must be determined (1) whether the reference is "within the field of the inventor's endeavor," and (2) if not, whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved." Because the Poehlman reference discloses seed certification practices that are not applicable to the activities of farmers or grain and food processors, Applicants submit that the Poehlman reference is not "within the field of the inventor's endeavor." Furthermore, because the scale of operations for production of certified seed as disclosed in the Poehlman reference versus that for farming and processing grain as claimed herein is significantly different, Applicants submit that the Poehlman reference is not "reasonably pertinent to the particular problem with which the inventor was involved." Therefore, based on the two-step test, Applicants submit that the Poehlman reference is nonanalogous art, and is therefore not relevant in determining obviousness of the instant claims.

In view of the above, Applicants respectfully request that the rejection of claims 1-3, 6-10, 13-21, 22-25, 28-33, 36-39, and 43-51 under 35 U.S.C. §103 be withdrawn.

Claims 4, 5, 26, and 27 stand rejected under 35 U.S.C. §103 as being unpatentable over the Poehlman reference in view of the Reuters reference in further view of the Lander reference (document AU from Applicant's 1449). This rejection is respectfully traversed.

The Examiner stated that the Lander reference discloses using genetic tests to distinguish among genotypes and that the 1 or 0.01% levels can be achieved by increasing the size of sample. The Examiner asserted that it would have been obvious to one of ordinary skill in the art

at the time of the invention to modify the steps as disclosed in the Poehlman reference as modified by the Reuters reference by using genetic testing (DNA fingerprinting) as disclosed in the Lander reference in the certifying step so as to increase the purity of seed planted or use as a processed seed product so as to increase yield by not having off-types.

The Lander reference discusses a DNA-based assay that compares two separate samples to determine whether or not one sample is identical to the other sample. No specific motivation to combine is found in the Lander reference. The Lander reference makes only a brief mention of determining the similarities and differences among plants. See, page 6. The Lander reference makes no mention whatsoever of testing populations of seeds for contamination (*i.e.*, "keeping seed pure"). Thus, the Lander reference does not pertain to the problem of minimizing seed contamination. Therefore, improper hindsight has been used to combine the cited references. The Lander reference contains no specific suggestion whatsoever to use DNA-based technology to assay a potentially heterogeneous sample for the level of contamination with genetically modified seeds. Thus, the combination of the Reuters reference in view of the Poehlman reference further in view of the Lander reference fails to provide a reasonable expectation in achieving the claimed methods.

The Examiner considers the power to reduce type I error (α level) to be a function of individuals sampled in a population. Applicants agree that this is a correct statement of a general statistical rule. However, the Examiner also reasoned that detecting 1, 0.1% or 0.01% contamination "can be achieved by increasing the number of loci sampled." Applicants respectfully submit that the Examiner's logic is incorrect. Increasing the number of loci sampled will not reduce type I error because the number of loci to be detected is the number of transgene loci that are potential contaminants. Increasing the number of loci tested may increase the ability to determine genetic similarity, which is of interest to Lander. See, page 2. However, if none of the additional loci tested are a transgene locus, they provide no information about the level of GMO contamination. The Lander reference contains no specific suggestion whatsoever to use DNA-based technology to assay a potentially heterogeneous sample for the level of contamination with genetically modified seeds. Thus, the combination of the Reuters reference in view of the Poehlman reference further in view of the Lander reference fails to provide a reasonable expectation in achieving the claimed methods.

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In view of the above, Applicants respectfully request that the rejection of claims 4, 5, 26, and 27 under 35 U.S.C. §103 be withdrawn.

Claims 11, 12, 34, and 35 stand rejected under 35 U.S.C. §103 as being unpatentable over the Poehlman reference in view of the Reuters reference in further view of the Montanari reference (5,478,990; document AD on Applicant's 1449). This rejection is respectfully traversed.

The Examiner states that the Montanari reference discloses the use of ID tracking food products from point of origin. The Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method described in the Poehlman reference as modified by the Reuters reference by using a tracking ID from point of origin through the processing phase so as to track contaminants such as pathogens. The Examiner also asserted that the Montanari reference discloses establishing an ID number when the crop is harvested.

The Montanari reference relates to a tracking system for food packages to identify the source of the product in a particular food package. The Montanari reference generally relates to a process for following the processing history of an animal from the time an animal is slaughtered until food products have been packaged for shipment. The Montanari reference also discusses the use of a tracking system to identify the source of a particular package of a food product. The Montanari reference is directed primarily at animals and provides no suggestion as to how contamination of non-GMO processed grain could be reduced or eliminated. The Poehlman reference in view of the Montanari reference does not teach or suggest that seed stock could have been grown, harvested, processed and certified to produce grain having less than 5% contamination by genetically modified seeds.

In view of the above, Applicants respectfully request that the rejection of claims 11, 12, 34, and 35 under 35 U.S.C. §103 be withdrawn.

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CONCLUSION

Applicant asks that claims 1-51 be allowed. Enclosed is a \$200 check for the fee for a Petition for Two-Month Extension of Time. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 1, 2002

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